

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

HETERO USA, INC., HETERO LABS LTD., and  
HETERO LABS LTD. UNIT-VI,

Defendants.

C.A. No. 1:24-cv-01025-JLH

**HETERO'S OPPOSITION TO INGENUS'S MOTION TO STAY**

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Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (collectively, “Hetero” or “Defendants”) respectfully submit that Plaintiff Ingenus Pharmaceuticals, LLC’s (“Ingenus”) motion to stay should be denied. Ingenus’s motion completely side-steps the fact that Ingenus is collaterally estopped from continuing to assert infringement in this case. This case should not be stayed; rather, it should proceed expeditiously to final judgment.

In support of its request to stay the case, Ingenus offers various prudential reasons why it believes a stay would be appropriate. Not only do these proffered reasons fall short of the mark, the Federal Circuit has squarely rejected the argument that a case should be stayed when subject to collateral estoppel as “in effect disput[ing] the finality of the . . . judgment” and contradicting the “vast weight of case law supports according the . . . judgment full collateral estoppel effect.” *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1380–81 (Fed. Cir. 1999). Ingenus’s request for a stay should be denied.

## **I. PROCEDURAL BACKGROUND**

Ingenus filed a lawsuit against Hetero on September 11, 2024, asserting that Hetero infringed U.S. Patent No. 10,993,952 (“the ’952 Patent”) under the Hatch-Waxman Act. D.I. 1. Under the Court’s schedule, the parties will submit their joint claim construction chart on July 7, 2025 and begin claim construction briefing on July 21, 2025. D.I. 20. This matter is currently set for trial on August 17, 2026, and the thirty-month stay expires on March 11, 2027. *Id.*

On May 9, 2025, in *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.), the Northern District of Illinois court granted summary judgment for Nexus and held that all of the claims of the ’952 patent were invalid. D.I. 50-1,

Exhibit A. Specifically, the Northern District of Illinois determined that the term “stable,” which is present in all of the ’952 patent claims, is indefinite:

the ’952 Patent has a term which could be ascertained by different measures, those measures could yield different results, and neither intrinsic nor extrinsic evidence indicates which to use. The term is thus indefinite.

*Id.* at p. 12. The Northern District of Illinois entered final judgment, which Ingenus appealed on June 2. D.I. 50-2, Exhibit B.

Because the Northern District of Illinois held that the ’952 patent—also asserted here—is invalid, Hetero reached out on May 16, 2025 and requested that Ingenus agree to entry of final judgment of invalidity in this case under the doctrine of collateral estoppel. Exhibit 1. Ingenus reviewed Hetero’s applicable case law but declined to agree to the final judgment and instead agreed to discuss the matter further. *Id.* While Ingenus initially advised it would be available to discuss the issue on May 22, Ingenus pushed the discussion to the following week. *Id.* The parties were finally able to discuss the Northern District of Illinois’s decision on May 30. *Id.* The parties had a second meet and confer on June 2 and a third discussion on June 9. Declaration of W. Weeks, ¶ 6. During those meet and confers, the parties discussed the proposed summary judgment and the possible stay of some upcoming deadlines, but Ingenus did not seek to substantively discuss any outstanding discovery or claim construction issues. *Id.*, ¶ 7.

During the meet and confers, counsel for Ingenus agreed that Hetero should be permitted to file a summary judgment motion in this case based on collateral estoppel. *Id.*, ¶ 8. And after the meet and confer on June 2, Ingenus drafted and circulated a proposed stipulation reflecting that representation. Exhibit 2. The proposed stipulation states that “Ingenus agrees, subject to prior approval from the Court, that Hetero should be permitted to file a case dispositive motion on the basis described above.” Exhibit 2, Draft Stipulation at 2.

Based upon its conversations with Ingenus, Hetero circulated on June 9 a proposed joint letter to the Court requesting a status conference and a proposed extension of the deadlines related to claim construction briefing. Declaration of W. Weeks, ¶ 11. Counsel responded on June 10, stating that it would not join in the request for a status conference or the extension of deadlines, but that it would not oppose Defendants' request for leave to file their proposed summary judgment motion or the request for a status conference. D.I. 51 at ¶ 16.<sup>1</sup> Hetero filed its request for status conference on June 10. Rather than waiting for the status conference, on June 13, Ingenus filed an opposed motion to stay the case pending the resolution of the appeal. D.I. 50.

## II. ARGUMENT

### A. Legal Framework

"It is undisputed that as a result of collateral estoppel, a judgment of invalidity in one patent action renders the patent invalid in any later actions based on the same patent." *MaxLinear, Inc. v. Cf Crespe LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (quotation omitted). Thus, the Federal Circuit has consistently given broad effect to the defense of issue preclusion based on a district court decision invalidating a patent in a wide variety of procedural contexts:

The Supreme Court has held that a defense of issue preclusion applies where a party is "facing a charge of infringement of a patent that has once been declared invalid," even though the party asserting the defense was not a party to the action where the patent was invalidated. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*,

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<sup>1</sup> Ingenus accuses Hetero of misrepresenting Ingenus's position on summary judgment. D.I. 50 at 2. In its letter, Hetero stated that Ingenus did not oppose Hetero's request for a status conference or Hetero filing a motion for summary judgment on the grounds that Ingenus is collaterally estopped from asserting infringement in this case by the final judgment of invalidity in the Northern District of Illinois. D.I. 48 at 1. There was no misrepresentation. As counsel for Ingenus states in his declaration, Ingenus advised Hetero on June 10, 2025, that "it would not oppose Defendants' request for leave to file their proposed summary judgment motion" or the request for a status conference. D.I. 51 at ¶ 16. *See also* Exhibit 2, Draft Stipulation at 2 (stipulation drafted by Ingenus memorializing their representation that "Ingenus agrees, subject to prior approval from the Court, that Hetero should be permitted to file a case dispositive motion on the basis described above.").

402 U.S. 313, 349–50, 91 S.Ct. 1434, 28 L. Ed. 2d 788 (1971). We have similarly held that “once the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under principles of collateral estoppel.” *Mendenhall v. Barber–Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994); *see In re Cygnus Telecomms. Tech., LLC, Patent Litig.*, 536 F.3d 1343, 1349 (Fed. Cir. 2008); *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379 (Fed. Cir. 1999). It is also established that issue preclusion applies even though the precluding judgment (Newegg) comes into existence while the case as to which preclusion is sought (this case) is on appeal. *Mendenhall*, 26 F.3d at 1583–84 (invalidity decision rendered while case on appeal); *Dana Corp. v. NOK, Inc.*, 882 F.2d 505, 508 (Fed. Cir. 1989) (invalidity decision at Federal Circuit issued while case being briefed on appeal).

*Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1315 (Fed. Cir. 2015) (collecting cases and describing the breadth of the Federal Circuit’s application of issue preclusion).

## **B. The Stay Should Be Denied.**

### **1. Hetero Is Entitled To Judgment Of Invalidity.**

Ingenus’s motion for a stay should be denied because Hetero is entitled to judgment as a matter of law. On May 9, 2025, the Northern District of Illinois entered final judgment invalidating all claims of the ’952 patent. *See Ingenus Pharm., LLC v. Nexus Pharm., Inc.*, No. 1:22-cv-02868, D.I. No. 215, 216 (N.D. Ill. May 9, 2025). These are the same claims of the same patent that are asserted against Hetero in this litigation.<sup>2</sup>

As the Federal Circuit has made clear, “once the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under the principles of collateral estoppel.” *See*

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<sup>2</sup> This patent was also the subject of another litigation, now settled, between Ingenus and Accord Healthcare, Inc. that was assigned to Your Honor. *See* Case No. 1:23-cv-00377-JLH.



*Pharmacia & Upjohn Co.*, 170 F.3d at 1379 (quoting *Mendenhall v. Barber–Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994)).

Thus, the District of Delaware has expressed “doubts that it has discretion to decline to apply collateral estoppel for equitable reasons in a case like this when all the requirements are otherwise met,” and has routinely applied collateral estoppel to claims held invalid by other courts. *See Biogen Int’l GmbH v. Amneal Pharms. LLC*, 487 F. Supp. 3d 254, 268 (D. Del. 2020); *Wireless Discovery LLC v. eHarmony, Inc.*, 654 F.Supp.3d 360 (D. Del., 2023); *IBM v. Rakuten, Inc.*, 2022 WL 17848779, No. 21-461-GBW, D.I. 230 (D. Del., Dec. 22, 2022).

Ingenus’s appeal of the Northern District of Illinois judgment has no impact on the application of collateral estoppel in this case because the “law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court’s holding.” *Pharmacia & Upjohn Co.*, 170 F.3d at 1381 (quoting *Deposit Bank v. Board of Councilmen of City of Frankfort*, 191 U.S. 499 (1903)); *see also PureWick Corp. v. Sage Prods., LLC*, No. 22-cv-102, 2023 WL 2734779, at \*11 (D. Del. Mar. 31, 2023) (“[T]he pendency or possibility of an upcoming appeal in *PureWick I* is likewise no basis for a stay here. Collateral estoppel applies regardless.”).

Ingenus does not offer any rebuttal to these cases. Instead, it simply ignores the substance of the collateral estoppel issue entirely and argues that the case should be stayed for prudential reasons. The Federal Circuit, however, has squarely rejected the argument that a stay should apply to litigation otherwise subject to the preclusive effect of a judgment of invalidity in another court.

In *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, the Federal Circuit considered an appeal from a district court’s judgment that was based on the preclusive effect of another court’s decision (referred to as the *Mova* case). The patentee in that case argued “that the district court should have stayed the proceedings pending the resolution of its motion in *Mova* for JMOL/new

trial and its possible appeal.” 170 F.3d at 1379-80. The Federal Circuit, however, rejected that argument as “in effect disput[ing] the finality of the *Mova* judgment,” which would contradict the “vast weight of case law supports according the *Mova* judgment full collateral estoppel effect.” *Id.* at 1381.

Had Ingenus wanted to avoid the collateral estoppel effect of the Northern District of Illinois judgment, it needed to move to stay entry of *that* judgment pending appeal—not ask for a stay here. *See Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 37 n.10 (D.D.C. 2000) (“District court decisions have res judicata and collateral estoppel effect and are binding on the parties unless a stay pending appeal is granted.”) (citing *Pharmacia & Upjohn Co.*, 170 F.3d at 1381; *Deering Milliken, Inc. v. FTC*, 647 F.2d 1124, 1128–29 (D.C. Cir.)). Because Ingenus failed to do so, the Northern District of Illinois’ judgment is final and has preclusive effect here. Ingenus’s request for a stay should therefore be denied.

## **2. Ingenus’s Arguments For A Stay Are Without Merit.**

Ingenus asserts that Delaware courts routinely apply the three factors listed in *Enhanced Sec. Research, LLC v. Cisco Sys., Inc.*, 2010 WL 2573925, at \*3 (D. Del. June 25, 2010), “when staying patent litigation pending *ex parte* reexamination or *inter partes* review.” D.I. 50 at 5, n.4. The pendency of an *ex parte* reexamination or *inter partes* review by the patent office, however, does not have preclusive effect—unlike a district court judgment of invalidity. Thus, these factors are not the appropriate measure of how to proceed here in light of the clear preclusive effect of the Northern District of Illinois decision. Regardless, even if the Court were to look to these factors for guidance, Ingenus’s arguments in favor of a stay are without merit.

First, Ingenus asserts that “a stay will simplify issues for trial.” D.I. 50 at 5. In support of this assertion, it says that in the event it loses its appeal, there will be no trial in this case, and that that the indefiniteness issue will be resolved by the Federal Circuit either way. But that is equally

true if the Court grants summary judgment. Ingenus's only other argument is that a stay will obviate the need to decide whether collateral estoppel applies.<sup>3</sup> Ingenus, however, has offered no substantive argument as to why collateral estoppel does not clearly apply here under binding Federal Circuit and Supreme Court precedent that Hetero cited in its letter requesting a status conference (which was previously shared with Ingenus). *See* D.I. 48. Thus, Ingenus has failed to show how a stay would simply issues for trial here.

Second, Ingenus asserts that the case is "effectively" stayed. Not only is that assertion wrong, it is also irrelevant. The sole patent asserted against Hetero in this case has been declared invalid in a final district court judgment with preclusive effect in this case. Under binding Federal Circuit and Supreme Court precedent, Hetero is entitled to judgment as a matter of law and this case should be terminated. There is no reason to proceed with further discovery in this case.

When the Northern District of Illinois decision came out, Hetero promptly raised it with Ingenus. In the three meet and confers that followed, the parties agreed to extend interim deadlines for six weeks while the parties determined how to proceed. Declaration of W. Weeks, ¶ 7. During the parties' meet and confers, Ingenus never sought to substantively discuss the discovery issues it raises in its motion. *Id.* Now Ingenus suggests that somehow this amounts to an effective stay of the litigation. It does not. Hetero is prepared to complete document production by the substantial completion deadline in this case and move forward with fact depositions, if needed. However,

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<sup>3</sup> Ingenus suggests in passing that a stay will save it the trouble of refileing the case. D.I. 50 at 5. Presumably Ingenus would appeal any adverse judgment in this case, *see* D.I. 50 at 4, but if not, it would waive any challenge to the judgment. Either way, there will not be any need for Ingenus to refile its case against Hetero.

because Ingenus is now collaterally estopped from asserting infringement, this case can and should be resolved now without further discovery.

### **3. Hetero Will Be Prejudiced By A Stay.**

Because collateral estoppel applies, Hetero is entitled to judgment as a matter of law in this case. Under the carefully struck balance of the Hatch-Waxman Act, such judgment will terminate the 30-month stay of approval of Hetero's ANDA application. 21 U.S.C. §§ 355(j)(5)(B)(iii)(I)(aa). The termination of the 30-month stay is necessary for Hetero to obtain final approval of its ANDA and to launch its ANDA Product. Although Hetero does not currently have FDA approval, at the time FDA is prepared to approve the ANDA, such approval should not be blocked by an improper stay in this court.

The 30-month stay in this case is scheduled to end on March 11, 2027. D.I. 50 at 1. Even if Ingenus is successful in its appeal of the Northern District of Illinois judgment, and this litigation resumed immediately after the resolution of the appeal, the parties would still need to complete fact and expert discovery and conduct claim construction before this case would be ready for trial. Under Ingenus's proposal, the 30-month stay will expire long before that happens.<sup>4</sup>

Ingenus's proposed method of addressing this issue is unworkable. Ingenus suggests that under its proposed stay, "[s]hould Hetero receive FDA approval and have an imminent planned or actual product launch, the Parties can notify the Court and request any emergency relief at that time."<sup>5</sup> D.I. 50 at 3. But there is no reason to burden the Court with emergency motions to decide collateral estoppel when that issue can, and should, be decided now.

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<sup>4</sup> A court may also shorten the 30-month stay if the patent owner fails "to reasonably cooperate in expediting the action." 21 U.S.C. §§ 355(j)(5)(B)(iii).

<sup>5</sup> Ingenus's suggestion also ignores the fact that FDA cannot issue final approval while the 30-month stay is in place.

On the other hand, if Ingenus wants to preclude a potential product launch while its appeal is pending, the correct procedure is to seek such relief from the Federal Circuit pending appeal (which it has not done in the *Nexus* appeal in any event). *See Astellas Pharma Inc. v. Lupin Ltd.*, 2024 WL 1759149 at \*1, No. 23-819-JFB-CJB, (D. Del. April 24, 2024). Any such request made in this Court, however, would have to be denied, as collateral estoppel would apply in any temporary restraining order or injunction proceeding here.

As the Federal Circuit has explained, “it is clear from the case law that has developed since *Blonder–Tongue* that an inappropriate inquiry is whether the prior finding of invalidity was correct; instead, the court is only to decide whether the patentee had a full and fair opportunity to litigate the validity of his patent in the prior unsuccessful suit.” *Pharmacia & Upjohn Co.*, 170 F.3d at 1380 (quoting *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705 (Fed. Cir. 1983)). Moreover, even “that inquiry into whether the plaintiff was afforded a full and fair opportunity to litigate is quite narrow and does not involve a judgment on the merits.” *Id.* There is no suggestion that Ingenus lacked a fair opportunity to litigate validity before the Northern District of Illinois.

Thus, in seeking emergency relief, Ingenus would be, in effect, asking for a temporary restraining order or injunction based on an invalid patent. Because a patent owner is not entitled to an injunction or a temporary restraining order where the patent “is not likely to withstand an invalidity challenge,” any such motion by Ingenus would fail. *Astellas Pharma Inc.*, 2024 WL 1759149 at \*1; *see also ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1355–56 (Fed. Cir. 2015) (“[T]he injunctions had to be reversed following the final judgment of patent invalidity.”).

### **III. CONCLUSION**

For the foregoing reasons, the motion for stay should be denied.

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